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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/765,754 | 01/27/2004 | Richard P. Rava | 301505.1363-110 | 1899 |

207 7590 09/01/2006

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EXAMINER

SMITH, RUTH S

ART UNIT PAPER NUMBER

3737

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,754

Applicant(s)

RAVA ET AL.

Examiner

Ruth S. Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,690,966. Although the conflicting claims are not identical, they are not patentably distinct from each other because they involve an obvious broadening of the patented claims. The specific parameters set forth regarding the laser light are well known operating parameters in the diagnostic optical art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4,6-12,14,16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in view of Muller and Williamson et al. Kittrell et al disclose a spectroscopic diagnostic system and method for measuring tissue. The system includes a laser for emitting radiation and a fiber optic cable optically coupled to the laser to deliver the radiation to the tissue and detect radiation from the tissue. Kittrell et al disclose that any number of characteristics can provide spectroscopic signals useful in diagnosing tissue. Kittrell et al disclose that Raman scattering as well as fluorescence can be used to diagnose tissue. Kittrell et al also disclose the need to remove background light from the detected signal. Muller discloses a molecular spectroscopic diagnostic system and method for measuring tissue. Muller discloses using laser Raman spectroscopy to diagnose a body condition. Muller also discloses the use of infrared radiation in order to avoid the disturbance by fluorescence caused by high fluorescence background levels. It would have been obvious to one skilled in the art to have modified Kittrell et al such that it performs Raman spectroscopy in view of the teachings of Kittrell et al that such is a known type of optical measurement of tissue and to have further modified Kittrell et al such that it operates in the infrared range to avoid to disturbance due to background fluorescence. The use of a spectroscope and CCD for detecting Raman spectra is old and well known as shown for example by Williamson et al. It would have been obvious to one skilled in the art to have further modified Kittrell et al such that the analyzer used comprises a spectrometer and a CCD detector. The modification merely involves the substitution of one well known type of

detector and analyzer for another. The modified system would inherently be capable of detecting the light with the CCD for a period of 5 minutes or less. It is a well known expedient in the medical art to reduce the amount of time necessary to collect data used to provide a diagnosis. Therefore, one skilled in the art would have necessarily taken advantage of this inherent capability of the modified system. With respect to claims 14,18, the specific optimum wavelength selected in the infrared range would have been an obvious selection of known operating wavelengths.

Claims 5,13,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in view of Muller and Williamson et al as applied to claims 1,10,14 above, and further in view of Wyatt. Wyatt discloses the use of an infrared laser light source to examine tissue where the output power of the source is within the range set forth in the claims. It would have been obvious to one skilled in the art to have further modified Kittrell et al such that the laser emits light within a range of 2 to 20 mW. Such a modification involves the selection of a known operating parameter in an optical system for examining tissue.

Claims 1,4,6,7,9,14,16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al ('410) in view of Williamson et al. Alfano et al disclose all of the claimed elements except for the use of a spectroscope and CCD. The use of a spectroscope and CCD for detecting Raman spectra is old and well known as shown for example by Williamson et al. It would have been obvious to one skilled in the art to modified Alfano et al such that the analyzer used comprises a spectrometer and a CCD detector. The modification merely involves the substitution of one well known type of detector and analyzer for another. The modified system would inherently be capable of detecting the light with the CCD for a period of 5 minutes or less. It is a well known expedient in the medical art to reduce the amount of time necessary to collect data used to provide a diagnosis. Therefore, one skilled in the art would have necessarily taken advantage of this inherent capability of the modified system.

Claims 2,3,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al in view of Williams et al as applied to claims 1,7 above, and further in view of Kittrell et al. Kittrell et al disclose a spectroscopic diagnostic system and method for measuring tissue. The system includes a laser for emitting radiation and a fiber optic cable optically coupled to the laser to deliver the radiation to the tissue and detect radiation from the tissue. Kittrell et al disclose that any number of characteristics can provide spectroscopic signals useful in diagnosing tissue. Kittrell et al disclose that Raman scattering as well as fluorescence can be used to diagnose tissue. Kittrell et al also disclose the need to remove background light from the detected signal. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the background components are removed from the detected light in order to provide a more accurate diagnosis.

Claims 5,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al in view of Williams et al as applied to claims 1,14 above, and further in view of Wyatt. Wyatt discloses the use of an infrared laser light source to examine tissue where the output power of the source is within the range set forth in the claims. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the laser emits light within a range of 2 to 20 mW. Such a modification involves the selection of a known operating parameter in an optical system for examining tissue.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al ('410) in view of Williamson et al, Andersson-Engels et al and Kittrell et al. Alfano et al disclose all of the claimed elements except for the use of a spectroscope and CCD. The use of a spectroscope and CCD for detecting Raman spectra is old and well known as shown for example by Williamson et al. It would have been obvious to one skilled in the art to modified Alfano et al such that the analyzer used comprises a spectrometer and a CCD detector. The modification merely involves the substitution of one well known type of detector and analyzer for another. The modified system would inherently be capable of detecting the light with the CCD for a period of 5 minutes or

less. It is a well known expedient in the medical art to reduce the amount of time necessary to collect data used to provide a diagnosis. Therefore, one skilled in the art would have necessarily taken advantage of this inherent capability of the modified system. Alfano et al disclose a method of examining tissue to determine the presence of cancer using IR Raman spectroscopy. Andersson-Engels et al disclose that spectroscopy can be used to determine the presence of atherosclerosis in arteries in addition to determining the presence of cancer. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the method is used to determine the presence of atherosclerotic tissue inasmuch as it is well recognized that light spectroscopy technology is equally applicable to both the detection of cancer and atherosclerosis. Kittrell et al disclose a spectroscopic diagnostic system and method for measuring tissue. The system includes a laser for emitting radiation and a fiber optic cable optically coupled to the laser to deliver the radiation to the tissue and detect radiation from the tissue. Kittrell et al disclose that any number of characteristics can provide spectroscopic signals useful in diagnosing tissue. Kittrell et al disclose that Raman scattering as well as fluorescence can be used to diagnose tissue. Kittrell et al also disclose the need to remove background light from the detected signal. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the background components are removed from the detected light in order to provide a more accurate diagnosis.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al ('410) in view of Williamson et al, Andersson-Engels et al and Kittrell et al as applied to claim 10 above, and further in view of Wyatt. Wyatt discloses the use of an infrared laser light source to examine tissue where the output power of the source is within the range set forth in the claims. It would have been obvious to one skilled in the art to have further modified Alfano et al such that the laser emits light within a range of 2 to 20 mW. Such a modification involves the selection of a known operating parameter in an optical system for examining tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Ruth S. Smith', is positioned above the printed name and title.

Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS